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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/003,215	10/30/2001	Grant L. Schoenhard	13727US01	4991

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EXAMINER

JAGOE, DONNA A

ART UNIT

PAPER NUMBER

1614

DATE MAILED: 07/21/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

**Advisory Action**

Application No.

10/003,215

Applicant(s)

SCHOENHARD, GRANT L.

Examiner

Donna Jagoe

Art Unit

1614

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 15 April 2004 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

**PERIOD FOR REPLY** [check either a) or b)]

- a) ☒ The period for reply expires 6 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on \_\_\_\_\_. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☐ The proposed amendment(s) will not be entered because:
- (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);
  - (b) ☐ they raise the issue of new matter (see Note below);
  - (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
  - (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: \_\_\_\_\_.

3. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.
4. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☐ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: \_\_\_\_\_.

Claim(s) objected to: \_\_\_\_\_.

Claim(s) rejected: 28-33.Claim(s) withdrawn from consideration: 34 and 35.

8. ☐ The drawing correction filed on \_\_\_\_\_ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_.
10. ☐ Other: \_\_\_\_\_

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Continuation of 5. does NOT place the application in condition for allowance because: applicant's argument appears to be directed to the amount of opioid receptor antagonist in a range of from 0.0001-100  $\mu$ m. The dosage range of the enhancing agents recited in Broder et al. is 0.1 to 15 mg/kg of patient body weight (column 11, lines 55-58). Naloxone, having a molecular weight of 363.84 g/mol. Translating Broder et al. to  $\mu$ m,  $(0.1\text{mg/kg}) \times 70\text{ kg} = 7\text{ mg}$ .  $7\text{ mg} \times 1\text{g}/1000\text{mg} = 7/1000\text{ g}$ .  $7/1000 \div 363.84 = \text{moles naloxone} = 1.92 \times 10^{-5}\text{ mol} = 0.2\text{ umol}$ . Since the dosage of 0.2  $\mu$ m would be encompassed by the 0.0001-100 $\mu$ m of the instant claims the dosage instantly claimed is inherent in the teaching of Broder et al. Broder et al. teaches that p-glycoprotein inhibitors increase oral bioavailability of specific target drugs such as paclitaxel. The p-glycoprotein inhibitors or orally administered enhancing agents include naloxone, naltrexone and nalmeferene (column 10, lines 28-31). The co-administration of enhancing agents promotes oral bioavailability of the target agents (such as paclitaxel) and also enables their use in the treatment of tumors at sites highly protected by multi drug resistance (MDR) (column 15, line 65 bridging to column 16, line 6). The fact that applicant has identified the claimed opioid inhibitors as "an opioid inhibitor of the ABC transporter protein" does not change the fact that applicant's claims are drawn to a composition comprising an opioid inhibitor such as naltraxone, nalfeferene and naloxone combined with a chemotherapeutic agent such as a taxane. Attention is directed to General Electric Company v. Wabash Appliance Corporation et al 37 USPQ 466 (US 1938), at 469, speaking to functional language at the point of novelty as herein employed: "the vice of a functional claim exists not only when a claims is "wholly" functional, if that is ever true, but when the inventor is painstaking when he recites what has already been seen, and then uses conveniently functional language at the exact point of novelty". Functional language at the point of novelty, as herein employed by Applicants, is further admonished in University of California v. Eli Lilly and Co. 43 USPQ2d 1398 (CAFC 1997) at 1406: stating this usage does "little more than outline goals appellants hope the recited invention achieves and the problems the invention will hopefully ameliorate".

Further, regarding the composition, it is well settled that the recitation of a new intended use for an old product does not make a claim to that old product patentable. See In re Spada, 911 F.2d 705, 708, 15 USPQ2d 1655, 1657 (Fed. Cir. 1990) ("The discovery of a new property or use of a previously known composition, even when that property and use are unobvious from prior art, can not impart patentability to claims to the known composition."); Titanium Metals Corp. of Am. v. Banner, 778 F.2d 775, 782, 227 USPQ 773, 778 (Fed. Cir. 1985) (composition claim reciting a newly discovered property of an old alloy did not satisfy section 102 because the alloy itself was not new); In re Pearson, 494 F.2d 1399, 1403, 181 USPQ 641, 644 (CCPA 1974) (intended use of an old composition does not render composition claim patentable); In re Zierden, 411 F.2d 1325, 1328, 162 USPQ 102, 104 (CCPA 1969) (" [M] ere statement of a new use for an otherwise old or obvious composition cannot render a claim to the composition patentable."); In re Sinex, 309 F.2d 488, 492, 135 USPQ 302, 305 (CCPA 1962) (statement of intended use in an apparatus claim failed to distinguish over the prior art apparatus); In re Hack, 245 F.2d 246, 248, 114 USPQ 161, 162 (CCPA 1957) ("the grant of a patent on a composition or a machine cannot be predicated on a new use of that machine or composition"); In re Benner, 174 F.2d 938, 942, 82 USPQ 49, 53 (CCPA 1949) ("no provision has been made in the patent statutes for granting a patent upon an old product based solely upon discovery of a new use for such product").

